



STATE OF MARYLAND

# DHMH

Maryland Department of Health and Mental Hygiene  
Office of Health Care Quality  
Spring Grove Center • Bland Bryant Building  
55 Wade Avenue • Catonsville, Maryland 21228-4663

*Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Dennis R Schrader, Secretary*

Thank you for making sure you are in compliance with Maryland's COMAR laboratory regulations, and renewing your laboratory license on schedule.

You will no longer receive a full renewal "application", it is no longer required.

If no changes to your current license are needed, we require that the lab director still signs the blank change form and submit a completed test menu page for all of your testing. This will indicate to us that the lab director acknowledges that no changes are required and we have the correct test information on the license.

If there is a change to your current laboratory license information, such as ownership, tax ID, name of laboratory, testing changes, laboratory closing, or address changes, complete the change form with dates of change, returning it signed with the completed test menu page. If the laboratory director is being changed from the director named on the current license, the change form must also be accompanied with a copy of the highest degree earned diploma or transcript, any clinical license held, and any board certifications or continuing medical education credits.

Submit application materials to:

Laboratory Licensing  
55 Wade Ave  
Bland Bryant Bldg.  
Catonsville, MD 21228

Sincerely,

Paul Celli, Laboratory Certification Program Manager  
Office of Health Care Quality, Maryland DHMH



Maryland Department of Health and Mental Hygiene  
Office of Health Care Quality – Laboratory Licensing Programs  
Spring Grove Center – Bland Bryant Building  
55 Wade Avenue, Catonsville, MD 21228  
Phone: 410.402.8025 Fax: 410.402.8213

Office Use Only

Date Received:

Date Completed:

## Laboratory Licensing Change Form

This form is for changes made during the renewal process only. Please provide us with the changes in the fields below along with the effective date of the change. Please check the **NO CHANGES** box on page 2 if there are no changes being made during this license cycle. Whether there are changes or no changes, please also complete the attached test menu to include all of your current testing. For a change of Director, a copy of the Director's medical license, medical diploma and board certification must be submitted. Please send diploma, board certification and CV for a PhD Director. CLIA certificate of compliance and PPM labs must submit a CLIA 116 application as well to update director. CLIA certificate of accreditation labs must contact their accreditation agency to update director.

### FOR RENEWAL PURPOSES ONLY

\*\*\*THIS FORM MUST BE SIGNED BY THE DIRECTOR FOR ALL CHANGES TO BE VALID.\*\*\*

Current Name of Lab: \_\_\_\_\_

State Lab ID # \_\_\_\_\_ Federal CLIA #: \_\_\_\_\_ Is this CLIA a multisite? Y N

Laboratory Name: \_\_\_\_\_ Date of Change: \_\_\_\_\_

Owner: \_\_\_\_\_ Date of Change: \_\_\_\_\_

Tax ID #: \_\_\_\_\_ Date of Change: \_\_\_\_\_

Director: \_\_\_\_\_ Date of Change: \_\_\_\_\_

Physical Address: \_\_\_\_\_ Date of Change: \_\_\_\_\_

Mailing/Billing Address: \_\_\_\_\_ Date of Change: \_\_\_\_\_

Telephone #: \_\_\_\_\_ Date of Change: \_\_\_\_\_

Fax #: \_\_\_\_\_ Date of Change: \_\_\_\_\_

Please list the tests you are adding or deleting from your current test menu. Please use the chart below and indicate for each test the instrument/kit used as well as the effective date of change.

### Changes/Additions/Deletions to Tests

Test Name	Kit/Instrument Used	Add	Delete	Date of Change
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

Change State License Status to:

☐ Letter of Exception      ☐ General Permit

Date of Change: \_\_\_\_\_

Change my CLIA Certification Status to: (must submit with a CMS-116, both forms must then be mailed to our address)

☐ Waiver      ☐ Compliance      ☐ Provider Performed Microscopic Procedures (PPMP)

☐ Accreditation with which program? \_\_\_\_\_

Date of Change: \_\_\_\_\_

Our office has closed and/or discontinued all clinical testing. Date of Change: \_\_\_\_\_

**\*\* ☐ No Changes (Please check if no changes are being made) \*\***

Print Laboratory Director's Name: \_\_\_\_\_

Laboratory Director's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## IV. Schedule A - General Permit

\*\*\* If you are only performing tests on Excepted list, Schedule B, do not use this section\*\*\*

<b>Chemistry</b>  <input type="checkbox"/> Routine <input type="checkbox"/> Blood Gas <input type="checkbox"/> Endocrinology <input type="checkbox"/> Toxicology: Drugs of Abuse <input type="checkbox"/> Toxicology: Therapeutic <input type="checkbox"/> Toxicology: Heavy Metals <input type="checkbox"/> Radioimmunoassay	<b>Genetics</b>  <input type="checkbox"/> Routine <input type="checkbox"/> Molecular <input type="checkbox"/> Cytogenetics	<b>Forensic Toxicology</b>  <input type="checkbox"/> Toxicology: Job Related	<b>Microbiology</b>  <input type="checkbox"/> Bacteriology <input type="checkbox"/> Parasitology <input type="checkbox"/> Mycology <input type="checkbox"/> Mycobacteriology <input type="checkbox"/> Virology	<b>Health Awareness *</b>  <input type="checkbox"/> Cholesterol/Lipids <input type="checkbox"/> Glucose Finger Stick <input type="checkbox"/> Hemoglobin A1c  <small>* performed at health fairs not routine chemistry lab *must be CLIA waived</small>
<b>Immunohematology/ Blood Bank</b> <input type="checkbox"/> ABO/Rh/Non Trans- fusion/Transplant <input type="checkbox"/> ABO/Rh <input type="checkbox"/> Antibody Detection <input type="checkbox"/> Antibody Identification <input type="checkbox"/> Compatibility Testing	<b>Hematology</b>  <input type="checkbox"/> Routine <input type="checkbox"/> Coagulation	<b>Molecular Biology</b>  <input type="checkbox"/> Nucleic Acid Probes <input type="checkbox"/> PCR Amplifications <input type="checkbox"/> Recombinant Nucleic Acid Techniques	<b>Pathology</b>  <input type="checkbox"/> Histopathology <input type="checkbox"/> Dermatopathology <input type="checkbox"/> Oral Pathology <input type="checkbox"/> Cytology-GYN <input type="checkbox"/> Cytology-Non- GYN	<b>Immunology</b>  <input type="checkbox"/> General Immunology <input type="checkbox"/> Syphilis Serology <input type="checkbox"/> Histocompatibility

## V. Schedule B - Excepted Tests \*

\* Note: Not all tests excepted by Maryland regulations are waived by CLIA. You can check the test categories for CLIA at  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/search.cfm>

<b>Chemistry</b> <input type="checkbox"/> CLIA waived blood lipid analysis for cholesterol, HDL, LDL, and triglycerides. <input type="checkbox"/> Dipstick Glucose <span style="float: right;">BNP <input type="checkbox"/></span> <input type="checkbox"/> Dipstick Urinalysis <span style="float: right;">Microscopic Urinalysis <input type="checkbox"/></span> <input type="checkbox"/> Dipstick Microalbumin & creatinine, urine <input type="checkbox"/> Fructosamine (whole blood) <input type="checkbox"/> <input type="checkbox"/> Glucose (FDA Home Device) <input type="checkbox"/> Hemoglobin A1c (Glycohemoglobin) <input type="checkbox"/> Waived Whole Blood Lead Testing <input type="checkbox"/> CLIA Waived Urine Drug Screen	<b>Hematology</b>  <input type="checkbox"/> Fern Test <input type="checkbox"/> Hematocrit <input type="checkbox"/> Hemoglobin <input type="checkbox"/> Nitrazine Test <input type="checkbox"/> Semen analysis, qualitative <input type="checkbox"/> Sick Cell Testing <input type="checkbox"/> CLIA Waived PT/INR
<b>Immunology</b>  <input type="checkbox"/> Bladder marker, H-related protein, qualitative <input type="checkbox"/> H.Pylori (whole blood) <input type="checkbox"/> Heterophyle AG (whole blood) <input type="checkbox"/> Mono Slide Test <input type="checkbox"/> NMP Bladder Marker, qualitative <input type="checkbox"/> Rheumatoid Factor <input type="checkbox"/> Urine Pregnancy Test	<b>Microbiology</b>  <input type="checkbox"/> Dermatophyte Screen <span style="float: right;">Trichomonas vaginalis antigen <input type="checkbox"/></span> <input type="checkbox"/> Bacterial Sialidase <input type="checkbox"/> Gram Stain <span style="float: right;">Adenovirus antigen eye fluid <input type="checkbox"/></span> <input type="checkbox"/> Group A Strep Screen (non-culture) <input type="checkbox"/> Influenza Antigen (nasal or throat swab) <input type="checkbox"/> KOH Preparation <input type="checkbox"/> Occult Blood <input type="checkbox"/> Occult Blood, gastric <input type="checkbox"/> Pinworm Prep <input type="checkbox"/> Urine Colony Count (no ID) <input type="checkbox"/> Wet Mount